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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,642	06/18/2001	Denisa D. Wagner	CFBF-P02-004	3076

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BOSTON, MA 02110-2624

EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. 09/8864 ✓	Applicant(s) WAGNER
Examiner Gomez	Art Unit 644

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6/18/01
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 39-88 is/are pending in the application.
- 4a) Of the above claim(s) 39-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 39-88 is/are allowed.
- 6) ☐ Claim(s) 39-88 is/are rejected.
- 7) ☐ Claim(s) 39-88 is/are objected to.
- 8) ☒ Claim(s) 39-88 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/18/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner. SEE OFFICE ACTION
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on 6/18/01 is: a) ☐ approved b) ☒ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s)
- 4) ☐ Interview Summary (PTO-413) Paper No(s)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. Applicant's amendment, filed 6/18/01 (Paper No. 4), has been entered.  
Claims 1-38 have been canceled.  
Claims 39-88 have been added.
2. In order to consistent with copending applications USSNs 08/948,393 and 09/436,076; the following restriction has been set forth herein.

Prior to setting forth the restriction requirement, it is pointed out that the claims are drawn to patentably distinct methods relying upon patentably distinct products. The instant methods and compositions rely upon P-selectin ligands such as sialyl Lewis x, sialyl Lewis a, P-selectin, PSGL-1, 160 kD monospecific P-selectin ligand, P-selectin mimic or P-selectin mimic or antibodies thereto which differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims, because these are not proper species. Further, it is noted that pages 6-12 of the instant specification discloses a number of patentably distinct agents, which may be subject to further restriction and/or species election. Applicant is invited to clearly elect a single Group as it reads on a particular therapeutic agent and to provide an appropriate claim that reads on the elected invention. The Groups set forth below appear to read on the claims as currently recited, but may be subject to further Restriction and/or species election depending on the claimed recitation.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 39-55, 60-68, 71-74, 76-82, 84-85, 86-88, drawn to methods of treating atherosclerosis, wherein the agent is sialyl Lewis x classified in Class 514, subclass 23.

II. Claims 39-55, 60-68, 71-74, 76-82, 84-85, 86-88, drawn to methods of treating atherosclerosis wherein the agent is sialyl Lewis a, classified in Class 514, subclass 23.

III. Claims 39-56, 60-68 71-74, 76-82, 84-85, 86-88, drawn to methods of treating atherosclerosis , wherein the agent is polyactosaminoglycan, classified in Class 514, subclass 23.

IV. Claims 39-56, 60-68, 70 71-74, 76-82, 84-85, 86-88, drawn to methods of treating atherosclerosis wherein the agent is heparin oligosaccharides, classified in Class 514, subclass 23.

V. Claims 39-56, 60-68, 71-74, 76-82, 84-88, drawn to methods of treating atherosclerosis, wherein the agent is carbohydrate containing 2,6 sialic acid, classified in Class 514, subclass 23.

VI. Claims 39-56, 60-68, 71-74, 76-82, 84-88, drawn to methods of treating atherosclerosis wherein the agent is Lewis x 3'-O-sulfate classified in Class 514, subclass 23.

VII. Claims 39-53, 58, 60-68, 71-88 drawn to methods of treating atherosclerosis wherein the agent is PSGL-1, classified in Class 514, subclass 8.

VIII. Claims 39-53, 58, 60-68, 71-74, 76-88 drawn to methods of treating atherosclerosis wherein the agent is a 160 kD P-selectin ligand, classified in Class 514, subclass 2.

IX. Claims 39-53, 58, 60-68 71-74, 76-82, 84-85, 86-88 drawn to methods of treating atherosclerosis wherein the agent is a P-selectin mimic, classified in Class 514, subclass 2.

X. Claims 39-52, 58, 60-68 71-74, 76-82, 84-85, 86-88 drawn to methods of treating atherosclerosis wherein the agent is P-selectin ligand mimic, classified in Class 514, subclass 2.

XI. Claims 39-52, 59, 60-68 71-74, 76-82, 84-85, 86-88 drawn to methods of treating atherosclerosis wherein the agent is derived from snake venom, classified in Class 424, subclass 542.

XII. Claims 39-52, 59, 60-68 71-74, 76-82, 84-85, 86-88 drawn to methods of treating atherosclerosis wherein the agent is derived from a plant extract, classified in Class 424, subclass 195.1.

XIII. Claims 39-52, 57, 60-68 71-74, 76-82, 84-85, 86-88 drawn to methods of treating atherosclerosis wherein the agent is P-selectin-specific antibody, classified in Class 514, subclass 8.

XIV. Claims 39-52, 57, 60-68 71-74, 76-82, 84-85, 86-88 drawn to methods of treating atherosclerosis wherein the agent PSGL-1-specific antibody, classified in Class 424, subclass 130.1.

XV. Claims 39-52, 57, 60-68 71-74, 76-82, 84-88 drawn to methods of treating atherosclerosis wherein the agent is a 160 kD P-selectin ligand-specific antibody, classified in Class 424, subclass 130.1.

XVI. Claims 39-56, 60-68 71-74, 76-82, 84-88 drawn to methods of treating atherosclerosis wherein the agent is a mucin-like molecule, classified in Class 424, subclass 501.

XVII. Claim 69, drawn to compositions comprising the agent sialyl Lewis x classified in Class 514, subclass 23.

XVIII. Claim 69, drawn to compositions comprising the agent sialyl Lewis a, classified in Class 514, subclass 23.

XIX. Claim 69, drawn to compositions comprising the agent polyactosaminoglycan, classified in Class 514, subclass 23.

XX. Claim 69, drawn to compositions comprising the agent heparin oligosaccharides, classified in Class 514, subclass 23.

XXI. Claim 69, drawn to compositions comprising the agent carbohydrate containing 2,6 sialic acid, classified in Class 514, subclass 23.

XXII. Claim 69, drawn to compositions comprising the agent Lewis x 3'-O-sulfate classified in Class 514, subclass 23.

XXIII. Claim 69, drawn to compositions comprising the agent PSGL-1, classified in Class 514, subclass 8.

XXIV. Claim 69, drawn to compositions comprising the agent 160 kD P-selectin ligand, classified in Class 514, subclass 2.

XXV. Claim 69, drawn to compositions comprising the agent P-selectin mimic, classified in Class 514, subclass 2.

XXVI. Claim 69, drawn to compositions comprising the agent P-selectin ligand mimic, classified in Class 514, subclass 2.

XXVII. Claim 69, drawn to compositions comprising the agent derived from snake venom, classified in Class 424, subclass 542.

XXVIII. Claim 69, drawn to compositions comprising the agent derived from a plant extract, classified in Class 424, subclass 195.1.

XXIX. Claim 69, drawn to compositions comprising the agent P-selectin-specific antibody, classified in Class 514, subclass 8.

XXX. Claim 69, drawn to compositions comprising the agent PSGL-1-specific antibody, classified in Class 424, subclass 130.1.

XXXI. Claim 69, drawn to compositions comprising the agent 160 kD P-selectin ligand-specific antibody, classified in Class 424, subclass 130.1.

XXXII. Claim 69, drawn to compositions comprising the agent mucin-like molecule, classified in Class 424, subclass 501.

4. Inventions XVII-XXXII and I-XVI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

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In addition to the number of patentably distinct agents set forth in Groups XVII-XXXII, there are a number of known therapeutic regimens to treat atherosclerosis that do not include the agents set forth in XVII-XXXII. Furthermore, the agents set forth in XVII-XXXII can be used in a number of different assays other than the treatment of atherosclerosis. Therefore, they are patentably distinct.

5. Inventions I-XII are different methods, which require patentably distinct ingredients. Therefore, they are patentably distinct. The claimed methods employ various PSGs which are distinct because their structures and modes of action are different, which require non-coextensive searches. These PSGs are different with respect to biochemical properties; including primary, secondary and tertiary structure. These molecules do not share a substantial structural feature essential to a common utility. Therefore, they are patentably distinct.

6. Because these inventions are distinct for the reasons given above and the search required for any Group from Groups I-XXXII is not required for any other group from Groups I-XXXII and Groups I-XXXII have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

#### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

##### A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

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**B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Phillip Gambel, PhD.

Primary Examiner

Technology Center 1600

October 1, 2002